

**K073720 ESENSOR WARFARIN SENSITIVITY AND XT-8
INSTRUMENT**Jul 17, 2008
199 days to decisionK073720 · Product code: **ODW** · Toxicology
Source: <https://www.510kdatabase.net/k073720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytochrome P450 2c9 (cyp450 2c9) Drug Metabolizing Enzyme Genotyping System (ODW)
Date received	Dec 31, 2007
Decision date	Jul 17, 2008
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osmetech Molecular Diagnostics
Location	Pasadena, CA, US
Contact	ROBERT DICHECK
510(k) history	3 submissions · 3 cleared · 2008-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k073720/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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